

Election/Restriction

Applicants provisionally elect Group I, claims 1-11, drawn to compounds of formula I wherein Ar is a phenyl or a pyridyl, with traverse.

Unity of invention was found during the International stage. As shown in the International Search Report and the International Preliminary Examination Report, the claims were searched and examined together. As described in MPEP § 1850 subsection I, the unity of invention standard applicable to the International stage is equally applicable during the national stage. Furthermore in MPEP § 1850 subsection II, “the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Searching Authority.” The International Searching Authority and the International Examination Authority applying the correct standard for unity of invention under PCT Rules 13.1 and 13.2 found that unity exists. Since the search has already been conducted by the International Search Authority and the International Examination Authority and no lack of unity of invention has been found, and because the search of the provisionally elected Group I would be commensurate in scope with the other Groups since the same technical feature is shared by all the Groups, there would be no undue burden on the Examiner to examine all Groups in one application.

Moreover, PCT Article 27 entitled “National Requirements,” provides in part “(1) No national law shall require compliance with requirements relating to form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.” Thus under PCT Article 27(1), the issue of lack of unity of invention should not be raised in the national phase of a PCT application when the issue was not raised during the PCT phase. Because there was no lack of unity rejection during the international phase by the International Searching Authority or the International Examination Authority, such a restriction is unjustified in the national phase of the present application. Accordingly, Applicants respectfully request that the Examiner reconsider the restriction requirement and examine all the claims in one application.

Alternatively, Applicants respectfully request that at least Groups I and III be examined together in one application. Under the applicable standard, an application “shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.” (PCT Rule 13.1). Unity of invention is fulfilled “when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical feature. The expression ‘special technical feature’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” (PCT Rule 13.2).

The Examiner argues that the inventions of Groups I and III lack the same or corresponding special technical feature because the claimed invention encompasses different Ar substituents that are drawn to an improper Markush group on the grounds of lack of a common nucleus. Applicants respectfully disagree.

“When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) all alternatives have a common property or activity, and (B)(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives” (PCT Rule 13.2).

First, the present invention relates to isotope-labeled and radio-labeled compounds that bind to nicotinic receptors. Page 1, lines 5-6. Therefore the claimed compounds share a common property or activity. Furthermore, the compounds of the present invention share a common core structure as shown in formula I. Page 3, line 4 and claim 1. Therefore the compounds of the present invention belong to a proper Markush grouping and share the same technical feature. Accordingly, Applicants respectfully request that the Examiner reconsider the restriction requirement and examine at least the claims of Groups I and III in one application.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-11 under 35 U.S.C. §103 as allegedly obvious over Tracey et al. (U.S. Pat. No. 7,238,715, hereinafter “Tracey”) and further in view of Rogers et al. (U.S. Application No. 2004/0157878 A1, hereinafter “Rogers”). The Examiner alleges that claim 12 of Tracey teaches the compound of the present invention and that this compound would inherently have the tritium isotope. The Examiner further alleges that the compound of claim 12

of Tracey could be combined with the radiolabeled compounds of Rogers to make the compounds of the present invention. Applicants respectfully disagree and traverse the rejection.

"An obviousness argument based on structural similarity between claimed and prior art compounds 'clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [the prior art compound] as a lead compound.' *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009), citing *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007); see also *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (stating that "post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound" in the prior art).

The Patent Office has failed to establish a prima facie case of obviousness because there is no showing why the person of ordinary skill in the art would choose the compound of claim 12 of Tracey as a lead compound from among the multitude of compounds disclosed in Tracey.

Tracey discloses multiple compounds in the specification (column 10, lines 18-59 and Examples 2 and 7) and claims 9, 12, 17-22 and 24-26. Furthermore, Tracey discloses a very large genus of compounds described by formulas (I) - (IV). Column 8, line 1 through Column 10, line 46. These formulas describe a range of different core structures with multiple potential substitutions on each core structure. Column 8, line 1 through Column 10, line 46. Thus, Tracey discloses a huge number of compounds with the disclosure of formulas (I) – (IV). The Patent Office bears the burden of showing where the prior art suggests the compound of claim 12 of Tracey as the lead candidate. In the absence of such a showing, a prima facie case of obviousness based solely on structural similarity between claimed and prior art compounds has not been made.

Rogers does not correct this deficiency. Rogers also discloses a large number of compounds in the specification (paragraphs [0012] and [0042]-[0094]) and claims 3-6, 9, 10 and 12. Furthermore, formula I of Rogers requires that the compounds of the invention comprise a carbonyl group. Paragraph [0009]. The compound of claim 12 of Tracey does not comprise a carbonyl group. See Tracey, claim 12. Therefore Rogers does not suggest the compound of

claim 12 of Tracey as the lead candidate.

Since Tracey and Rogers do not provide any teaching for selecting the compound of claim 12 of Tracey as the lead candidate, whether or not this compound would inherently have the tritium isotope is moot. Similarly, whether or not Rogers or the references cited in the present specification suggest radiolabeling of the compound of claim 12 of Tracey is also moot. Reconsideration and withdrawal of the rejection is urged.

Double Patenting

The Examiner provisionally rejected claims 1-11 on the ground of nonstatutory obviousness double patenting over claims 12 and 19 of Application No. 12/321,951. Because this is a provisional double patenting rejection, Applicants will further respond as necessary once the claims are otherwise found allowable.

CONCLUSION

In view of the above remarks, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

This response is filed within the three-month period for response from the mailing of the Office Communication. No fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 15652-04303-US from which the undersigned is authorized to draw.

Respectfully submitted,

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